OCT 21 2011

510(k) Summary

Commwell Ltd. PhysioGlove ES Model I with ECG Analysis

510(k) Number K103791

Date:
October 18, 2011

Submitter:
Commwell Ltd.
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Device Trade Name:
PhysioGlove ES Model I with ECG Analysis

Common Name:
12-lead Diagnostic System with ECG Analysis Program

Classification:
Electrocardiograph System

Product Code:
DPS, MHX

Class:
II

CFR Reference:
21 CFR 870.2340

Predicate Devices:
- K050674, Commwell PhysioGlove ES Model I
- K092369, GE 12SL ECG Analysis Program

Intended Use / Indications for Use:

The PhysioGlove ES Model I is a reusable 12-lead diagnostic ECG examination system. The system can be used with 12-lead cables or the PhysioGlove device. When used with the PhysioGlove, it is intended to conduct an electrocardiogram. The diagnostic and automatic measurement features are not available. When used with a 12-lead cable, it is intended for use in resting diagnostic electrocardiograph examination of adults. The PhysioGlove ES Model I is intended for use in physician offices, hospitals, outpatient clinics, or similar settings by or on the order of a physician or similarly qualified healthcare professional. The device provides waveform parameters and ECG analysis for healthcare provider interpretation.

The PhysioGlove ES Model I ECG Analysis Program assists the physician in measuring and interpreting resting 12-lead EGGs for rhythm and contour information by providing an initial automated interpretation. Interpretation by the product is then confirmed, edited, or deleted by the physician. The analysis program is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The analysis program is intended for use in hospitals, outpatient clinics, emergency departments, and out-of hospital sites such as ambulances and patients' homes.

Device Description:

The PhysioGlove ES Model I is a diagnostic electrocardiograph for 12-Lead resting ECGs. The system consists of an electronics data acquisition unit and software that runs on a medical grade PC. The system uses either a standard, FDA-cleared, 10-electrode EGG cable, or the PhysioGlove to obtain ECG data from the patient. The electronics performs analog processing and analog to digital conversion of a 12 lead diagnostic ECG.

The digital packets from the front-end enter the PC via the USB port. The software for the PC performs a variety of functions, including patient registration, ECG display, and storage.

In addition the system provides ECG analysis. The ECG Analysis Program is a software algorithm only. When the system is used with the PhysioGlove, the ECG Analysis Program is not available.

The PhysioGlove ES Module I is intended to be marketed in two configurations.

- Configuration 1 – standard ES Model I without ECG analysis.
- Configuration 2 – standard ES Model I with ECG analysis.

Technological Characteristics - Components and Safety Features:

The PhysioGlove ES Model I with ECG analysis is for recording and analyzing diagnostic 12-lead ECG signals. The system is intended to be used with either a standard patient cable or the cleared PhysioGlove device (K083677). When used

with the PhysioGlove, the ECG analysis functionality is disabled. The system employs the same functional scientific technology as its predicate devices.

Determination of Substantial Equivalence:

The PhysioGlove ES Model I with ECG analysis has been modified from the predicate version (K050674) to include additional features to enhance performance and usability of the device, and to provide additional functionality with the introduction of the ECG analysis package (General Electric (GE) 12SL ECG Analysis Program approved under (K092369)). There have been no changes to the fundamental scientific technology of the system.

Summary of Non-Clinical testing:

There are no recognized consensus standards applicable to the EGG Analysis System algorithm. The EGG Analysis Program and its applications comply with the Guidances and/or Special Controls as outlined below and detailed in Section 16 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- *Requirements Reviews
- *Risk Analysis
- *Software Verification and Validation
- *Performance testing

The device was tested according to the following performance standards:

- Usability testing was done to demonstrate the efficacy of the PhysioGlove in its intended environment.
- IEC 60601-1-4 Programmable Electrical Medical Systems
- IEC 62304 Software Life Cycle for Medical Devices
- IEC 60601-2-51 Particular requirements for safety of electrocardiographs

In all instances, the device functioned as intended.

Summary of clinical testing:

The modifications made to the PhysioGlove ES Model I with ECG analysis did not require clinical testing to support substantial equivalence.

Conclusion:

The summary above shows there are no new questions of safety and effectiveness issues associated with the PhysioGlove ES Model I with ECG analysis when compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 21 2011

Crommwell Ltd.
c/o Mr. Irving Levy
Vice President
Rechov Yad Harutzim4
Kfar Saba
ISRAEL 44641

Re: K103791
Trade/Device Name: PhysioGlove ES Model I with ECG Analysis Program
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: September 21, 2011
Received: September 21, 2011

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K103791

Device Name:

PhysioGlove ES Model I with ECG Analysis Program

Indications for Use:

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Prescription Use ___X____ (Per 21 CFR 801.109 subpart D) OR Over the Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K103791